REMARKS

It is noted that the principal objection of the Office Action is that claims 1-3, 8-14, 17-19, 21-28, 30 and 31 are rejected under 35 USC 103(a) as being unpatentable over Jangula in view of Sempere. Claims 4-7 and 16 were rejected under 35 USC §103(a) as being unpatentable over Jangula and Sempere in view of Brunnberg et al. Claims 15 and 29 were rejected under 35 USC §103(a) as being unpatentable over Jangula and Sempere in view of Pizzino. Finally, claims 20 and 32 were rejected as being unpatentable over Jangula and Sempere in view of Brunnberg et al. and Pizzino. No amendments are offered to the claims in order to meet these objections because Applicant believes the claims currently filed are both structurally and functionally distinguishable over a combination of Jangula and Sempere, as will now be discussed.

The invention of this application is a safe needle-handling device in order to minimize the risk of needle-stick injuries to anyone using the needle, either for the purpose of self injection or by third parties (medical personnel) performing injections on others. A particular use with which this invention is concerned is to provide a safe handling device for a pen injector which is fitted with a fresh needle each time an injector is to be used and when the injector has been used, that needle must be disposed of safely.

Conventionally, a needle for a pen injector is provided in sterile packaging and with a sheath furnished over the needle, to protect that part of the needle which is inserted into a patient, either by the patient or some other operator. Before the pen injector is used, a protective cap is removed from the forward end of the injector and a fresh sheathed needle is removed from its sterile packaging, that needle then being threaded on to a boss at the forward end of the injector. After setting the injector to the appropriate dose, the sheath is removed from the needle, the injection is performed and then the needle must be removed from the injector, for disposal.

It is during the stage of needle removal and disposal that there is the most risk of a needle-stick injury. The hub of the needle must be grasped usually between the thumb and forefinger of one hand with the injector being held by the other hand and then the injector is

rotated to free the needle hub from the injector. Once done, the needle must be dropped into a safe container or otherwise disposed of, to minimize risk of injury to anyone in the vicinity. Re-sheathing of the needle, which would give a measure of protection is not normally performed because of the very high risk of a needle-stick injury in trying to thread the needle into the sheath, which must be held typically between the thumb and forefinger of one hand.

The device which is the subject of this invention is a major advancement in the safe handling of needles, and particularly those for use with pen injectors. With this invention, the handling device is configured to perform a three-fold purpose. Firstly, the device is adapted to remove the sheath from a needle provided on an injection device, such as a pen injector. Secondly, the device provides on the injector a safety shield to give protection to the de-sheathed needle. Thirdly, the device allows for the safe disposal of a used needle, minimizing the risk of needle-stick injury both during removal of the needle from the injector and in the subsequent disposal thereof.

Referring now to Jangula, this provides a device to assist the de-sheathing and re-sheathing (referred to in Jangula as "de-capping and re-capping") of a needle of a syringe, but is expressly designed for use with injectors for injecting radioactive materials, though it is recognized in the specification that the device may be used with other medicaments. The sole function of Jangula is to allow sheath removal and re-sheathing; it has no other functionality except for the possible shielding of the user's fingers from radioactive materials by the provision of bushing 46.

Jangula has no moving parts, and though the Examiner has referred to spring nut 52 as being the "spring means" of claim 1 of this application, in fact the spring nut merely serves the purpose of allowing the sheath to be grasped thereby for the purpose of de-sheathing. Once assembled as shown in Figure 4 of Jangula, no parts of the device have any relatively moving functionality. The spring nut 52 is clamped between stop surface 48 and adaptor 40. The sheath is engaged with the nut by relative rotation of the syringe with respect to the device such that on pulling the syringe away from the device, the sheath remains within the device. When the needle is to be re-sheathed, the needle is pushed back into the device and the syringe is then rotated in the opposite sense, so freeing the sheath from the nut.

There is nothing in Jangula that suggests the device of Jangula can be used for anything other than the removal of a sheath from a needle and the replacement of that sheath subsequent to the use of a needle. Jangula does not assist in the disposal of the needle following its use (other than the re-sheathing of the needle) and there is nothing in Jangula that teaches the protection of a needle in the period between the de-sheathing thereof and the re-sheathing, following use.

Turning now to Sempere, this is an example of many safety devices for use with medical needles. Sempere provides a needle mounted on a hub which is engageable with the spigot at the forward end of a syringe, together with a sleeve assembly to protect the needle until it is to be used. A cap for the sleeve is provided and which must be removed before the device can be used for performing an injection. On use, the sleeve slides rearwardly with respect to the sharp end of the needle, so allowing the needle to be inserted into a patient and following use, the sleeve slides forwardly again under the action of a compression spring. As is well known in this art, an automatic locking arrangement is provided to lock the sleeve in its forward position once it has moved there, following the performance of an injection. In this way, multiple use of the needle is prevented.

The device of Sempere is totally different both in concept and physical construction from that of Jangula. These two devices have totally different objectives, operate in completely different ways, and have quite distinct functionality. Even if the skilled man considered Sempere when reviewing the teaching of Jangula, there is no rational way in which the two devices could be combined, to achieve the device of this application.

The Examiner has contended that "it would have been obvious to a person having ordinary skill in the art ... to modify the bushing and sleeve of ... Jangula to remain upon the injector upon withdrawal of the carrier ...". This cannot be accepted and appears to be a simple matter of post-facto analysis. Most certainly it would not have been obvious to even the most skilled person in the art having regard to the totally different constructions of the two devices.

The bushing 46 of Jangula is locked into the main body by virtue of removable cap 30 which actually is screw-threaded into the body and serves the additional purpose of holding

the adaptor 30 and spring nut 52. There is no way in which Jangula can be modified, even by taking into account the teachings of Sempere, to make the bushing 46 removable and to remain on the needle of the syringe. Even if that could be achieved, there is no way in which that bushing on its own could then be slidable with respect to the syringe, to give protection to the needle both before and after the performance of an injection.

It would not be possible to modify Jangula to achieve the alleged functionality as expressed by the Examiner in the present Office Action. The devices of Jangula and Sempere are so totally different in concept and construction that the modification of one to take into account the teachings of the other undoubtedly would involve extensive activity.

Reference is now made to the analysis set out in paragraph 3 of the detailed action. This is incorrect in many respects and some of those will be itemized below.

Sub-paragraph b.

The Examiner indicates that bushing 46 is the equivalent of the sleeve of this application. The Examiner has indicated that the rear end of the bushing 46 is "adapted to receive the cylindrical body of the injector". This is not the case with Jangula. A consideration of Figure 2 shows that the cylindrical body of the injector cannot get anywhere near the bushing 46, which is buried inside the body of Jangula and is held there by removable cap 30.

Sub-paragraph d.

The Examiner indicates that the spring nut 52 is the equivalent of the spring means of this application. As noted above, there are no moving parts in Jangula and the nut is merely a "spring nut" in that its inner threads are springy, to allow the accommodation of a sheath. The nut itself performs no springing action on any other components and is clamped in a fixed position, between the adaptor 40 and an internal shoulder within the bushing 46, as shown in Figure 4.

Sub-paragraph e.

The body 12 of Jangula cannot possibly be considered to be the equivalent of the plug of this application. The body 12 is the principal part of the overall device 10 of Jangula and is not "projectable from the forward end thereof (the device)".

Sub-paragraph f.

The analysis in this paragraph cannot possibly be sustained having regard to the points raised above.

Essentially the same arguments apply in regards to the analysis of claims 21-23 found at page 5 of the Office Action. The Examiner has essentially copied forward the wording of the analysis of claim 1 and the same comments equally apply here.

The device of the present application is thus far removed conceptually from that of Jangula by itself or in combination with Sempere or any of the other documents mentioned in the Office Action. Taking Jangula as the starting point, no combination with any other cited document could possibly arrive at the safe handling device of this invention, for the several reasons already discussed above.

Further consideration of this application is requested, taking into account all of the foregoing comments.

Respectfully submitted,

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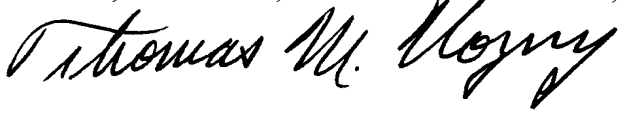

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